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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,512	06/29/2001	Christer Owman	07675.0001-03	4536

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EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	10

DATE MAILED: 04/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/893,512	Applicant(s) OWMAN, CHRISTER	
	Examiner Robert Landsman	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16 and 38-49* is/are pending in the application.

4a) Of the above claim(s) *45-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16 and 38-44* is/are rejected.

7)☒ Claim(s) *40, 41 and 44* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence Comparison* .

DETAILED ACTION

1. Formal Matters

A. Claims 16, 19, 25 and 26 were pending and were subject to restriction in Paper No. 10. In Paper No. 12, filed 2/19/03, Applicants elected Group I, claims 16 and 19 with traverse. Applicants added new claims 38-44, drawn to elected Group I, and new claims 45-49, drawn to process of using the protein of Group I and request that, of the product (i.e. protein) claims of Group I are found allowable, that these process claims be rejoined. If the product claims are found allowable, and the process claims (i.e. claims 45-49) are commensurate in scope with the allowable product claims and do not raise any issues under 35 USC 112, these process (i.e. method) claims will be rejoined.

B. Amendment D, filed 2/19/03, has been entered into the record. Applicants cancelled claims 19, 25 and 26. therefore, claims 16 and 38-49 are pending and claims 16 and 38-44 are the subject of this Office Action.

2. Declaration Regarding Sequence Errors

A. A Declaration was submitted by one of the inventors, Christer Owman, on 2/19/2003, stating that, during mutation experiments on clone Lyme21-9, sequence errors were discovered in the original sequence. Dr. Owman states that these errors were simple reading errors, with no deceptive intent. However, there is no statement in this Declaration stating that the clone identified as having sequencing errors was the exact clone as deposited with the ATCC. Therefore, a new Declaration to this effect should be submitted.

3. Claim Objections

A. Claims 40 and 41 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of previous claims 38 and 39, respectively. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 38 and 40 both recite a protein encoded for by plasmid Lyme21-9. Claims 39 and 41 both recite that the receptor is encoded for by SEQ ID NO:1. the only difference is the terminology used to define the receptor, "heptahelix" and "leukotriene B4." However, the sequence is identical in both cases.

B. Claim 44 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. It is not understood, respectfully, how one of skill in the art would be able to differentiate a receptor produced by recombinant means over one produced by non-recombinant means. These receptors would be identical.

4. Claim Rejections - 35 USC § 112, first paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 38 and 40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As stated in Applicants Amendment D, field 2/19/03, U.S. Patent regulations (37 C.F.R. 1.804(b)) and PTO rules (MPEP 2604.02) require that, when a deposit of a biological material is made after the effective filing date of the application, someone must corroborate that the deposited material is the material identified in the application. Since Lyme21-9 was deposited after the effective filing date of the present application, this requirement applies in the instant case. Until an appropriate Declaration to this effect is submitted, the claims are rejected as not being enabled for the protein encoded for by Lyme21-9.

5. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 16, 38-44 are rejected under 35 U.S.C. 102(a) as being anticipated by Yokomizo et al. (Nature 387:620-624, 1997). The claims recite a protein of SEQ ID NO:2. The claims recite that this protein can be recombinant, or is encoded for by SEQ ID NO:1, or plasmid Lyme21-9. Yokomizo et al.

teach a protein 100% identical to SEQ ID NO:2 (Sequence Comparison). Since this protein was produced from cloned DNA, it is recombinant. Regardless, protein produced recombinantly is inherently the same as that produced by non-recombinant means. Therefore, Yokomizo et al. also meet this claim limitation. Though Yokomizo et al. do not teach a polynucleotide 100% identical to SEQ ID NO:1, or encoded for by Lyme21-9, the protein encoded for by these polynucleotides is still 100% identical that of Yokomizo et al.

B. Claims 16, 38-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Akbar et al. (J. Biol. Chem. 271:18363-18367, 1996). The claims recite a protein of SEQ ID NO:2. The claims recite that this protein can be recombinant, or is encoded for by SEQ ID NO:1, or plasmid Lyme21-9. Akbar et al. teach a protein 100% identical to SEQ ID NO:2 (Sequence Comparison). Since this protein was produced from cloned DNA, it is recombinant. Regardless, protein produced recombinantly is inherently the same as that produced by non-recombinant means. Therefore, Akbar et al. also meet this claim limitation. Though Akbar et al. do not teach a polynucleotide 100% identical to SEQ ID NO:1, or encoded for by Lyme21-9, the protein encoded for by these polynucleotides is still 100% identical that of Akbar et al.

C. Claims 16, 38-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Raport et al. (J. Leuko. Biol. 59:18-23, 1996). The claims recite a protein of SEQ ID NO:2. The claims recite that this protein can be recombinant, or is encoded for by SEQ ID NO:1, or plasmid Lyme21-9. Raport et al. teach a protein 100% identical to SEQ ID NO:2 (Sequence Comparison). Since this protein was produced from cloned DNA, it is recombinant. Regardless, protein produced recombinantly is inherently the same as that produced by non-recombinant means. Therefore, Raport et al. also meet this claim limitation. Though Raport et al. do not teach a polynucleotide 100% identical to SEQ ID NO:1, or encoded for by Lyme21-9, the protein encoded for by these polynucleotides is still 100% identical that of Raport et al.

6. Conclusion

A. No claim is allowable.

ROBERT LANDSMAN
PATENT EXAMINER 4/14/03

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
April 14, 2003